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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0304]

Dietary Supplements Containing Ephedrine Alkaloids; Administrative Docket Update; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of certain documents to update the administrative docket of the proposed rule on dietary supplements containing ephedrine alkaloids. This action is being taken to ensure that interested persons are aware of the updated information. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing certain provisions of the proposed rule on dietary supplements containing ephedrine alkaloids, and establishing a new docket that will contain new adverse event reports and related information concerning these products.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS–7), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–6733.

SUPPLEMENTARY INFORMATION:

I. Background (Proposed Rule)

In the **Federal Register** of June 4, 1997 (62 FR 30678), FDA published a proposed rule on dietary supplements containing ephedrine alkaloids (the ''ephedrine alkaloids proposal''). That proposal would have established a finding that a dietary supplement is adulterated if it contains 8 milligrams or more of ephedrine alkaloids per single serving, required that the labels of products that contain ephedrine alkaloids state, ''Don't use this product for more than 7 days,'' required

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that contain ephedrine alkaloids state, ''Don't use this product for more than 7 days,'' required certain warning statements, and affected other aspects of product labeling for such products. FDA

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proposed this action after receiving over 800 adverse events associated with the use of dietary supplements that contained, or were suspected to contain, ephedrine alkaloids, and reviewing scientific literature and other data concerning ephedrine alkaloids. FDA received approximately 14,775 comments in response to the ephedrine alkaloids proposal.

II. Updated Information

FDA is updating the docket for the ephedrine alkaloids proposal with additional information, most of which was received after publication of the proposal.

FDA received 270 additional adverse event reports between February and September 1997. FDA added these adverse event reports to the ephedrine alkaloids proposal's docket in two submissions without formal clinical analysis. FDA did not rely on these 270 reports in the ephedrine alkaloids proposal because FDA received them after it began its analysis for the proposal.

FDA has received additional documentation (e.g., copies of product labels and labeling, information on how the consumers used the products at issue and available medical or other clinical records) concerning approximately 17 of the 270 adverse event reports the agency put in the docket after publication of the ephedrine alkaloids proposal. Consequently, FDA has reorganized these 17 reports to include the additional documentation that the agency has received, and it has redacted the files. FDA is now placing the 17 reorganized and redacted adverse event charts in the ephedrine alkaloids proposal's docket.

Should FDA receive additional information on the adverse events that are part of the administrative docket for the ephedrine alkaloids proposal, the agency will include it in that docket.

This updated information may be seen by interested persons at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/28/00

March 28, 2000

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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